

**SAFREL COUGH RELIEF- dextromethorphan hydrobromide capsule, liquid filled  
Safrel Pharmaceuticals, LLC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Safrel Cough Relief Dextromethorphan HBr 15 mg**

**Drug Facts**

**Active ingredient (in each softgel)**

Dextromethorphan HBr, USP 15mg

**Purpose**

Cough suppressant

**Use**

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

**Warnings**

**Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

**Ask a doctor before use if you have**

- a cough that occurs with too much phlegm (mucus)
- a cough that lasts or is chronic as occurs with smoking, asthma, or emphysema

**Stop use and ask doctor if** cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- do not take more than 8 capsules in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

adults and children 12 years and over	take 2 capsules every 6 to 8 hours, as needed
children under 12 years	do not use

**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

**Inactive ingredients**

FD&C Red No. 40, gelatin, glycerin, polyethylene glycol 400, propylene glycol, povidone, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?**

**1-844-384-3723**

Distributed by:

Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

[www.safrel.com](http://www.safrel.com)

**PRINCIPAL DISPLAY PANEL**

Safrel Dextromethorphan Softgels 15 mg - 100 ct

NDC 71309-601-10

**Safrel®**

**NON-DROWSY  
COUGH RELIEF**

Dextromethorphan HBr • 15 mg

**Adult Long-Lasting** FOR AGES 12 & OVER

Relieves Cough for up to 8 Hours  
Cough Suppressant

**100 SOFTGELS / 15 MG EACH**      **ACTUAL SIZE**

COMPARE TO THE ACTIVE  
INGREDIENT OF ROBUTUSSIN®  
LONG ACTING COUGH GELS®\*



DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.

**PEEL FOR WARNINGS & DIRECTIONS**  
LIFT HERE

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<b>Uses</b>	temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
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**Drug Facts (continued)**

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**Questions or comments?**  
1-844-384-3723 or [www.safrel.com](http://www.safrel.com)

\*This product is not manufactured or distributed by the owner of the registered trademark, ROBUTUSSIN® LONG ACTING COUGH GELS®.

Distributed by: Safrel Pharmaceuticals  
1200 Route 22 East, Suite 2000 • Bridgewater, NJ 08807  
(844) 384-3723 • [www.safrel.com](http://www.safrel.com)

## SAFREL COUGH RELIEF

dextromethorphan hydrobromide capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-601
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	IS3
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-601-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2022	
2	NDC:71309-601-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2022	
3	NDC:71309-601-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/28/2022	

**Labeler** - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 1/2023

Safrel Pharmaceuticals, LLC.